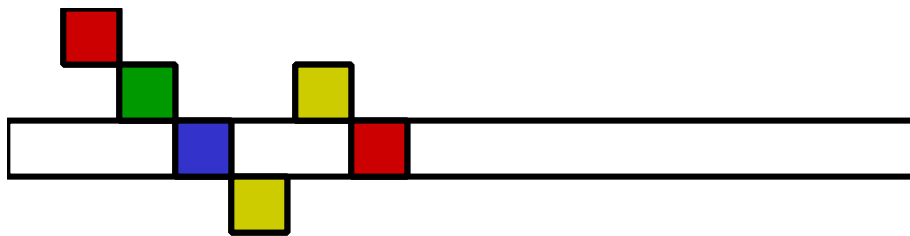


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DR. FIRESTONE: Thank you very much. I'd like to thank the sponsors of the workshop; this is a very impressive group of individuals.

The Office of Children's Health Protection was created by Carol Browner in 1997 to help implement Executive Order 13045 that Dr. Lynn Goldman talked about a little bit earlier, whose purpose was to require federal agencies to identify and assess children's environmental health risks.



OCHP's Science Activities for 2000



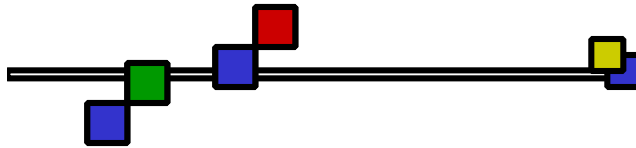
Michael Firestone, Ph.D., Science Director



Office of Children's Health Protection

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Working through the federal interagency task force formed as a result of EO 13045, which Dr. Goldman also mentioned very briefly, the Office of Children's Health Protection has worked with the other federal agencies to implement a new strategy on lead prevention and is working on a federal-wide strategy on asthma also. These strategies focus on research, mitigation, education and outreach.



Goal of the Strategy



To describe how OCHP can parlay its limited resources toward improving the scientific basis necessary for EPA and others to protect children from environmental hazards.

2

Office of Children's Health Protection

For example, the Office of Children's Health Protection has been developing educational materials, working with groups like the Boy and Girl Scouts and the 4-H Clubs, and has been developing other outreach materials with the health community.

Although EPA's Office of Children's Health Protection was only created two and a half years ago, and even though it only has a very small staff of about 15 people, it has a very broad group of responsibilities, as I just mentioned.

One of the other areas that this office is involved with is supporting an external advisory group called the Children's Health Protection Advisory Committee.

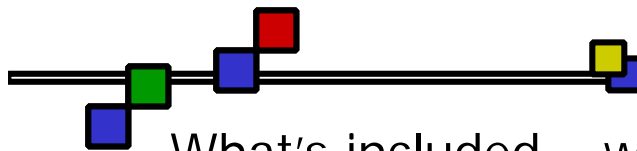
The science team, which I now head, having just joined the children's office a couple months ago, is basically trying to figure out at this point how to take a very small amount of resources -- three of us right now, although I'm trying to hire a couple more people -- and a small amount of money, and basically use that to catalyze efforts within the agency to move forward with children's environmental health protection.

What I'm going to try to do today is describe the progress I have made in the last three or four months of trying to figure out how we can parlay that small amount of resources to

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make a difference at EPA. What I am going to talk about today are the various science activities related to risk assessment guidance, science policies, surveys of the literature, and information sharing. What I won't talk about today is the area of basic research, which is the realm of our Office of Research and Development. And luckily we've had a number of very good speakers so far, with more to come, from EPA.

What is the role of the Office of Children's Health Protection and the science team? It's basically to be a catalyst, whether that means being a leader or a participant, providing seed money or staff support for various activities within the agency. We try to do a little bit of everything.



What's included – what's not



Included:

- Risk assessment guidance
- Testing guidelines/protocols
- Science policy
- Surveys of the recent scientific literature
- Information sharing through seminars, workshops, publications and practica



Excluded:

- Basic research (realm of EPA's Office of R&D)

Office of Children's Health Protection

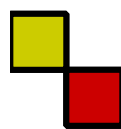
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One of the most surprising things I found on joining the children's office a couple of months ago occurred at my first meeting with the Children's Health Protection Advisory Committee. The children's advisory committee meetings are generally about a day-and-a-half to two-days and are often preceded by a full-day meeting of various work groups. I provide support for the Science and Research Work Group.

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One of the biggest messages I got from my first Science and Research Work Group meeting was that the agency, and our office in particular, need to do a much better job at trying to educate the public on how and where children are different from adults. I'm sure to everyone in this room, it's obvious that children are different from adults.

As a risk assessor, what I'm interested in answering is the question “are children different enough from adults that the way we test for toxicity and the way we conduct our risk assessments need to be changed from a process that's been developing over the last 30 years?” I think it's really critical though for our children's office at EPA to try to answer the basic question of how are children different from adults? What are the implications not only for risk assessors, but for policy-makers or risk managers, for health care practitioners, and also for parents who have children and have concerns about their children?



Project a – Contract with Dr. Linda Frazier/U. of Kansas to develop a primer re: chemical toxicity in the context of human development and susceptibility.

Project b – Contract with Dr. John Armstrong/Immunarm Inc. to develop a report reviewing how exposures to environmental agents may impact the developing immune system and lead to disease.



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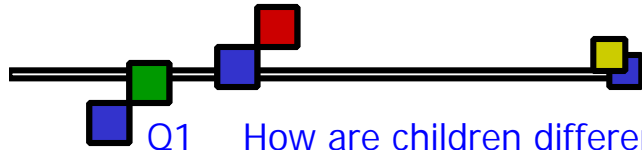
During the rest of my talk, I will organize the activities of the science team in terms of answering four basic questions. The first one has to do with how children are different.

The first thing I want to talk about are two projects that David Chen on the science team has been working on. The first deals with a contract with Dr. Linda Frazier who's here in the audience today, whose purpose is to develop a primer report on what is our current understanding of children's diseases and potential linkages to environmental exposures.

The second contract that Dr. Chen's working on is with Dr. John Armstrong, from Immunarm. Dr. Armstrong is here and he will be talking tomorrow on his activities for the science team related to developmental immunotoxicity.

In addition to those two projects, we're thinking about two new proposals. One is to take the results of this meeting and other recent efforts at EPA, and either put on a seminar series and/or possibly develop some review papers that explore the differences between children and adults.

This is with the idea of developing information for the Second International Conference on Children's Environmental Health, which now I understand will be held next September. The first major planning meeting is actually occurring today. A couple of the scientists here, including Dr. Lynn Goldman and Dr. Mark Miller, will be on that advisory committee trying to help us figure out whether and how we should go forward with that proposal.



Q1 How are children different from adults?

Proposal c – Hold a seminar series to explore differences, possibly focusing on specific organ systems such as the nervous, endocrine and immune systems - the results are intended to help inform next year's Second Int. Conference on Children's Environmental Health.

Proposal d – Conduct periodic searches of the scientific peer-reviewed literature related to assessing children's environmental health, posting the results on the Web, and summarizing key findings for the public.

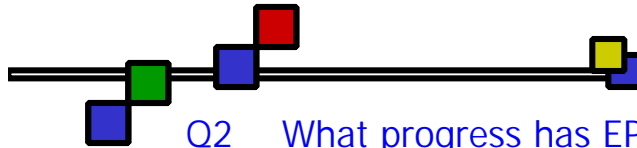
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Office of Children's Health Protection

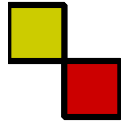
The second proposal relates to a frustration I have of coming into the children's health area -- although much of my previous experience within EPA related to children and pesticide exposure have dealt with the area -- and trying to get a hold of the latest papers on children's environmental health and trying to keep up with what's happening. We have such a small staff, we're so busy doing 29,000 different things, that just keeping up with the literature is a very difficult problem.

We have just begun exploring through the help of a contractor or with the National Laboratory of Medicine, developing a database on papers that have been published in the peer review literature that deal with chemical exposures in children and toxicity so that we have a resource not for just us at EPA but for everyone in the environmental community.

Question number two is: What kind of progress is EPA making? Although the Executive Order came out in 1997, Carol Browner in 1996 actually issued her first policy, which directed EPA staff to do a better job of considering and evaluating children's environmental risk. So the real question is since 1996 and 1997, how good of a job have we done?



Q2 What progress has EPA made toward assessing children's risk?



Project a – OCHP will host an internal agency meeting to evaluate standards/rules/regulations and ID serious data gaps that are an impediment to assessing children's risk. These data needs would be prioritized for consideration in EPA's research planning process.



Proposal b – To hold a series of internal-EPA practicum involving case studies so that the agency's program and regional offices can share its successes and target areas for future improvement.

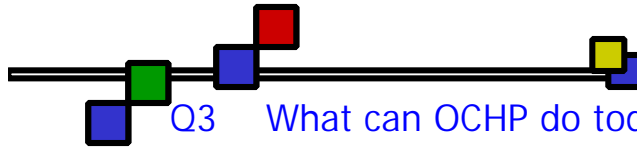


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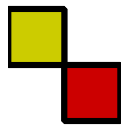
EPA has a new Deputy Administrator, Mike McCabe. At a recent Science Policy

Council meeting which involves the deputy administrator and the most senior officials in the various programs within EPA, they approved a couple of pilot studies for the agency to try related to our agency's recent development of a Science Inventory.

One of the two pilots that were approved was a proposal that our office put forward. This is to take a look at recent rules, regulations, and standards that have been promulgated within EPA over the last year or year and a half, and evaluate how good of a job we've been able to do in terms of assessing children's environmental risks.



Q3 What can OCHP do today to improve the science behind children's health protection?



Project a – Provide support for the Science & Research Workgroup of the Children's Health Protection Advisory Committee (e.g., review EPA's research strategy for children; develop principles for conduct of research with children).

Project b – Provide peer-review/involvement for agency assessments, guidance and science policies (e.g., Pesticide's Cumulative Risk Assessment Guidance and 10-X Policy; EPA's Dioxin Re-assessment; EPA's Cancer Risk Assessment Guidelines revision).



The project will also try to look at and help identify the data gaps and information gaps.

The pilot phase of this project is intended is to go back and try to feed that information back into both our own research program at EPA as well as efforts by others.

For example, the National Toxicology Program, will coordinate with EPA to develop toxicology information and other data that will be helpful for EPA to improve the way it does its risk assessments. If this is successful and it provides good information to feed back into our research planning process we will consider doing it again in the future.

The last proposal I have to help answer my second question, proposal D (sic), is something I'd like to follow up on after we complete this pilot study. That's the idea of within EPA and within our regions and program offices of trying to share our successes. Where we have been able to do a reasonable job of evaluating children's environmental health, we can share the information, and the methods and protocols between the various programs and offices within EPA.

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Question three relates to what are the day-to-day activities that we're working on within the Office of Children's Health Protection. These routine activities are twofold. One, I talked earlier about the external Children's Health Protection Advisory Committee one of the things we're doing is providing technical support to them. I listed a couple of the activities that the Science and Research Work Group of the advisory committee is working on this year, including reviewing ORD's draft research strategy for children's environmental risk. Another area that seems to be pretty hot now is the whole issue of the ethics of using children in research.

The other project under this relates to the day-to-day activities we do. A lot of it has to do with taking a look at the guidance and science policies and other things that come out within the agency, to take a look at -- either provide some peer involvement or peer review. And I put some examples here.

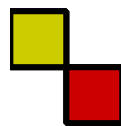
I was recently involved with reviewing the draft cumulative risk assessment guidance policy that is coming out of EPA's pesticide program -- a draft will likely be published for public comment sometime this summer, I expect.

Other examples include the dioxin risk assessment, which should hopefully be coming to fruition sometime this year. With respect to EPA's revision of its cancer risk assessment guidelines, we participated and helped plan a one-and-a-half-day workshop to discuss issues related to children, along with our Office of Research and Development at EPA, as well as NIEHS. What I would really love during this meeting is some feedback on what can we do in the future to help improve the risk assessment practices for children's health. That I've listed here in this next slide are several activities or projects that we're currently involved with either through helping fund or through providing some staff support.

The first has to do with working with ILSI, the International Life Sciences Institute, to develop a framework, and after that some guidance, on how to conduct children's risk


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assessments. The idea builds on what was done for ecological risk assessment where first a framework was developed and eventually a new set of guidelines was developed at EPA. I think it would build on the earlier efforts that ILSI completed in 1992 when it published a report on what was known about how children are different from adults. The second project on this slide represents EPA's commitment, both ORD as well as the children's office, to support the World Health Organization or WHO in updating their principles for children's risk assessments.



Project a – ORD and OCHP will work with ILSI to hold workshops leading to the possible development of a Framework and eventually Guidelines for assessing children's environmental health risks.

Project b – ORD and OCHP embarked in 1999 on a multi-year effort to support the World Health Organization in updating its principles for evaluating children's risks to chemicals.



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Office of Children's Health Protection

The next two projects, starting with project C here, has to do with an effort that's actually being led by EPA's Risk Assessment Forum, an organization of scientists within the Environmental Protection Agency, which is to define the minimal set of developmental stages which should be considered when assessing exposures.

The ultimate type of a risk assessment would be to follow an individual for every day of their life: As a fetus through birth, and then all the way up to old age, but obviously that's not possible. Right now it's not good enough to try to lump children ages one to six

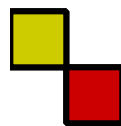
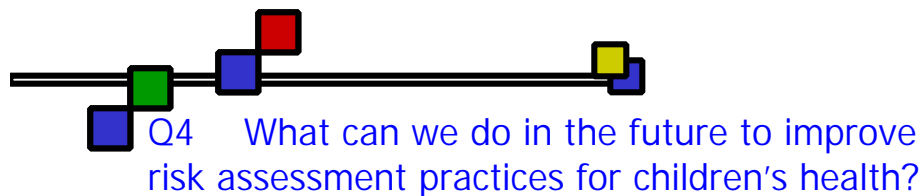
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together because their behavioral differences as well as their exposures are quite different.

One area that I've worked on has to do with how children are different, especially young children, in terms of pesticides exposure. One of the things that we know is that children are exposed because they're low to the ground, especially in their early stages as toddlers, they crawl around, they have lots of hand-to-mouth activity. Trying to understand that activity for a one-year-old or two-year-old is very different than it might be for a six-year-old who's doing very different types of activities.


Thus, the purpose of this workshop is to try to better define what some of those life stages are that all offices at EPA should be taking a look at.

And the last project here is really something that we're just providing some peripheral



Project c – EPA will hold a workshop to consider how developmental stages (based on behavior and physiology) in childhood might be utilized to classify critical exposure periods.

Project d – EPA, through it's Risk Assessment Forum and Pesticide's 10-X Task Force, is evaluating toxicity testing designs to consider the need for revised protocols or new studies necessary to fully evaluate children's risks.



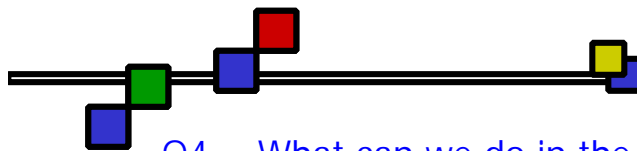
support to, and these are a couple of different efforts that overlap to some degree.

One is an effort led by Penny Fenner-Crisp and others in the pesticide program to refine their draft report, the so called “10-X report”, which takes a look at how we deal with the

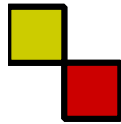
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FQPA safety factor. An agency wide task force is taking a look at public comments and based on that we'll revise the task force report.

The second has to do with another project from the agency's Risk Assessment Forum that deals with the whole process by which the agency sets reference doses. Part of both of those projects has to do with the types of toxicity tests we use now, considering ways to either revise or replace some of those tests in the future to get better information so that we can do a better job with assessing children's environmental health. I want to acknowledge Carol Kimmel's efforts in leading that reference dose task force.



Q4 What can we do in the future to improve risk assessment practices for children's health?



Proposal e – EPA, along with HHS and several other Federal Agencies have formed a planning group to examine implementing a longitudinal cohort study of environmental impacts on children and families. We are currently in the hypotheses development stage.



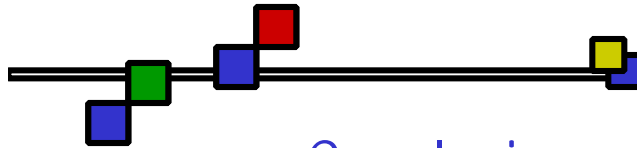
The last area that we wanted to get into for improving the future is a project that I'm sure most of you have heard about. This is the notion of establishing a new longitudinal cohort study of children and their families. The lead for this project at EPA is Carol Kimmel. This project is under the auspices of a federal-wide task force on children. At this point we're involved in establishing a management coordination team that would go across the various federal agencies, as well as developing agency planning teams.

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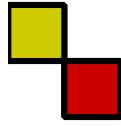
These planning teams are beginning to take a look at developing possible hypotheses that could be tested in such a study.

From EPA's vantage point, we'd like to do a better job of developing exposure data and then trying to link such data to specific environmental health impacts that might be seen through a study like this.

But I think in order for us to achieve this goal, we need to do something that NASA's tried to do, which is the cheaper, faster, better notion of figuring out how to monitor for exposure in the environment. The biggest problem with developing a cohort of a hundred thousand to a million individuals is obviously the cost. I think there's a lot of concern among agency scientists that we don't want to conduct a study like this if it means we're going to bankrupt every other science research area that we've been involved with. And so, the key here is to try to convince Congress and others that this is a sorely needed study.



Conclusion



This presentation described existing and proposed scientific projects supported by OCHP during 2000 designed to answer 4 questions related to the science behind EPA's efforts to assess children's environmental health risks.



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Office of Children's Health Protection

In conclusion, I've tried to describe some of the activities that a very small group within EPA, the Office of Children's Health Protection and more specifically its science team, has been involved with in trying to push the science forward, to try to be a catalyst for change at EPA. Anyway, thank you very much for your time. If you have any questions, if you have especially any good ideas on how we can help catalyze that change we'd very much appreciate it. Thank you. (Applause.)

(A question is posed from the audience, not at a microphone; inaudible.)

DR. BARONE: Michael, one question, maybe clarification about human testing and particularly childhood, or testing during childhood. I thought the Office of Pesticides had gone to the SAB with proposals and human testing was sort of ruled out based upon ethical grounds that pesticides were not of intrinsic therapeutic value. Is --

DR. FIRESTONE: Let me describe the current state of play, and also talk about what we mean by testing.

That you're referring to is a joint scientific advisory panel, including members from both the external peer review group that reviews pesticides issues – the FIFRA Scientific

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Advisory Panel, along with the Science Advisory Board, which is an external peer review panel for the whole agency, that took a look at the whole issue of ethics in human testing.

Their focus was primarily on toxicology testing. That panel has met twice.

The latest version of the report I saw needed a lot of work in order to just be clear about what advice they were offering to EPA. There is nothing conclusive yet out of that panel, although something may come out soon.

Additionally, the Children's Health Protection Advisory Committee's Science and Research Work Group is looking at the ethics of using children in research, which could potentially be a very broad area. It could include toxicity testing with children, although I seriously doubt that anyone would condone that type of a study, but it ranges all the way down to questions about exposure monitoring. It gets down even to issues of such as if we're looking at lead mitigation and we want to compare a group where we're trying to mitigate exposure with a control group, is it ethical not to do some form of remediation for that control group.

I hope that helps.